

CERTIFICATE

The undersigned authority has the honour to certify, in conformity with Article 6 of the Convention,

1) \* that the document has been served

- the (date) 7<sup>th</sup> June 2011
- at (place, street, number) 131 Front St. Hamilton

- in one of the following methods authorised by Article 5:

☒ (a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of Article 5 of the Convention.\*

☐ (b) in accordance with the following particular method:\*

☒ (c) by delivery to the addressee, who accepted it voluntarily.\*

The documents referred to in the request have been delivered to:

- (identity and description of person) Alicia Lambert
- relationship to the addressee (family, business or other): Administrator

2) \* that the document has not been served, by reason of the following facts:

~~(Unable to locate at 131 Front St. Hamilton)~~

In conformity with the second paragraph of Article 12 of the Convention, the applicant is requested to pay or reimburse the expenses detailed in the attached statement. \*

-- ANNEXES --

Documents returned:

In appropriate cases, documents establishing the service:

Done at 131 Front St. Hamilton, the 25<sup>th</sup> June 2011

Signature and/or stamp





# IN THE SUPREME COURT OF BERMUDA

Action No. 11SC00092

DANA-Farber Cancer Institute inc Plaintiff

Novartis International Pharmaceutical Ltd Defendant  
(Name of person or company to be served)

## AFFIDAVIT OF SERVICE

I, Frank C. Pate, Bailiff of the Supreme Court  
of Bermuda, Hamilton, Bermuda,

MAKE OATH and say as follows:-

On the 7<sup>th</sup> day of June, 2011, at 1:38 pm

I personally served  
(name of person)

Alicia Lambert (Adm)

with  
(list of  
documents)

Foreign Document

at  
(place of  
service)

"131 Front St. Hamilton

in the Islands of Bermuda.

(delete if .The person served is known to me personally. Or  
inappropriate) .The person served identified himself/herself to be the person so-named  
above.

Sworn at the city of Hamilton in the Islands of Bermuda)  
this 8<sup>th</sup> day of June 2011

Frank C. Pate

Before me:

George Fenech  
A COMMISSIONER OF OATHS



**THEODORE J. FOLKMAN**

Direct Dial: 617-226-3451

Direct Fax: 617-305-0651

Email: [tjf@murphyking.com](mailto:tjf@murphyking.com)

May 13, 2011

BY FEDEX

The Registry  
The Supreme Court  
113 Front Street  
Hamilton HM 11  
Bermuda

re: *Dana-Farber Cancer Institute, Inc. v. Gatekeeper Pharmaceuticals, Inc., Civ. A.  
No. 10-11613 (D. Mass.)*

Dear Sir or Madam:

I enclose the following documents in duplicate:

1. Request for Service Abroad of Judicial or Extrajudicial Documents
2. Summons in a Civil Action
3. Amended Counterclaims and Crossclaims of Gatekeeper Pharmaceuticals, Inc.

Would you please date-stamp the enclosed photocopy of this letter to acknowledge receipt and return it to me using the enclosed pre-paid Fedex airbill.

Sincerely,

A handwritten signature in black ink, appearing to read 'Theodore J. Folkman'.

Theodore J. Folkman

enclosures

596095

cc: Timothy T. Scott, Esq.  
Meredith M. Leary, Esq.  
Lisa J. Pirozzolo, Esq.

Professional Corporation  
Counsellors at Law

[www.murphyking.com](http://www.murphyking.com)

One Beacon Street  
21st Floor  
Boston, MA 02108-3107

Tel: 617-423-0400  
Fax: 617-423-0498

1055 Thomas Jefferson Street, N.W.  
Suite 400  
Washington, DC 20007-5211

Tel: 202-403-2100  
Fax: 202-429-4380

1359 Broadway  
Suite 2001  
New York, NY 10018-7833

Tel: 212-631-0223  
Fax: 212-624-0223

How to proceed:

# REQUEST FOR SERVICE ABROAD OF JUDICIAL OR EXTRAJUDICIAL DOCUMENTS

Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, signed at The Hague, the 15<sup>th</sup> of November 1965

## Identity and address of the applicant

Clerk of the  
United States District Court  
for the District of Massachusetts  
One Courthouse Way  
Boston, Massachusetts 02210  
USA

## Address of receiving authority

Registrar of the Supreme Court  
113 Front Street  
Hamilton HM 11  
Bermuda

The undersigned applicant has the honour to transmit – in duplicate – the documents listed below and, in conformity with Article 5 of the above-mentioned Convention, requests prompt service of one copy thereof on the addressee, i.e.

Novartis International Pharmaceutical Ltd.  
Hurst Holme  
12 Trott Rd.  
Hamilton, HM LX  
Bermuda

- ☒ (a) in accordance with the provisions of sub-paragraph (a) of the first paragraph of Article 5 of the Convention.\*
- ☐ (b) in accordance with the following particular method (sub-paragraph (b) of the first paragraph of Article 5):\*
- ☐ (c) by delivery to the addressee, if the addressee accepts it voluntarily (second paragraph of Article 5).\*

The authority is requested to return or to have returned to the applicant a copy of the documents - and of the annexes \* - with a certificate as provided on the next page.

## List of documents

1. Summons
2. Amended Counterclaims and Crossclaims of Gatekeeper Pharmaceuticals, Inc.

Done at Boston , the 5/13/2011

Signature and/or stamp



SARAH A. THORNTON

**SUMMARY OF THE DOCUMENT TO BE SERVED**

Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters,  
signed at The Hague, the 15th of November 1965

(Article 5, fourth paragraph)

**Identité et adresse du destinataire / Identity and address of the addressee / -----:**

Novartis International  
Pharmaceutical Ltd.  
Hurst Holme  
12 Trott Rd.  
Hamilton, HM LX  
Bermuda

**IMPORTANT**

LE DOCUMENT CI-JOINT EST DE NATURE JURIDIQUE ET PEUT AFFECTER VOS DROITS ET OBLIGATIONS. LES «ELEMENTS ESSENTIELS DE L'ACTE» VOUS DONNENT QUELQUES INFORMATIONS SUR SA NATURE ET SON OBJET. IL EST TOUTEFOIS INDISPENSABLE DE LIRE ATTENTIVEMENT LE TEXTE MEME DU DOCUMENT. IL PEUT ETRE NECESSAIRE DE DEMANDER UN AVIS JURIDIQUE.

SI VOS RESSOURCES SONT INSUFFISANTES, RENSEIGNEZ-VOUS SUR LA POSSIBILITE D'OBTENIR L'ASSISTANCE JUDICIAIRE ET LA CONSULTATION JURIDIQUE SOIT DANS VOTRE PAYS SOIT DANS LE PAYS D'ORIGINE DU DOCUMENT.

LES DEMANDES DE RENSEIGNEMENTS SUR LES POSSIBILITES D'OBTENIR L'ASSISTANCE JUDICIAIRE OU LA CONSULTATION JURIDIQUE DANS LE PAYS D'ORIGINE PEUVENT ETRE ADRESSEES A :

**IMPORTANT**

THE ENCLOSED DOCUMENT IS OF A LEGAL NATURE AND MAY AFFECT YOUR RIGHTS AND OBLIGATIONS. THE 'SUMMARY OF THE DOCUMENT TO BE SERVED' WILL GIVE YOU SOME INFORMATION ABOUT ITS NATURE AND PURPOSE. YOU SHOULD HOWEVER READ THE DOCUMENT ITSELF CAREFULLY. IT MAY BE NECESSARY TO SEEK LEGAL ADVICE.

IF YOUR FINANCIAL RESOURCES ARE INSUFFICIENT YOU SHOULD SEEK INFORMATION ON THE POSSIBILITY OF OBTAINING LEGAL AID OR ADVICE EITHER IN THE COUNTRY WHERE YOU LIVE OR IN THE COUNTRY WHERE THE DOCUMENT WAS ISSUED.

ENQUIRIES ABOUT THE AVAILABILITY OF LEGAL AID OR ADVICE IN THE COUNTRY WHERE THE DOCUMENT WAS ISSUED MAY BE DIRECTED TO:

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Il est recommandé que les mentions imprimées dans cette note soient rédigées en langue française et en langue anglaise et le cas échéant, en outre, dans la langue ou l'une des langues officielles de l'Etat d'origine de l'acte. Les blancs pourraient être remplis soit dans la langue de l'Etat où le document doit être adressé, soit en langue française, soit en langue anglaise.

*It is recommended that the standard terms in the notice be written in English and French and where appropriate also in the official language, or one of the official languages of the State in which the document originated. The blanks could be completed either in the language of the State to which the documents is to be sent, or in English or French.*

**Name and address of the requesting authority:**

U.S. District Court for the District of Massachusetts  
One Courthouse Way  
Boston, Massachusetts 02210  
USA

**Particulars of the parties: \***

The party interested in the transmission of these documents is: Gatekeeper Pharmaceuticals, Inc., c/o Timothy T. Scott, Esq., King & Spalding LLP, 333 Twin Dolphin Drive, Suite 400, Redwood Shores, California 94065, USA

**JUDICIAL DOCUMENT \*\***

**Nature and purpose of the document:**

The Summons and the Amended Crossclaims and Counterclaims give notice of Gatekeeper Pharmaceuticals's claims against Novartis International Pharmaceutical Ltd. and of the date on which an answer or motion is required.

**Nature and purpose of the proceeding and, where appropriate, the amount in dispute:**

Civil action for damages and equitable and declaratory relief. The amount in dispute is unliquidated.

~~XXXXXXXXXXXXXXXXXXXXXXXXXXXX~~  
~~Date and place for entering appearance: \*\*~~

~~COURT WHERE HAS GIVEN JUDGMENT \*\*~~

~~DATE OF JUDGMENT \*\*~~

**Time limits stated in the document: \*\***

An answer or a motion must be filed within 21 days after service of the summons and complaint.

**EXTRAJUDICIAL DOCUMENT \*\***

~~NATURE AND PURPOSE OF THE DOCUMENT:~~

~~TIME LIMITS STATED IN THE DOCUMENT \*\*~~

UNITED STATES DISTRICT COURT  
for the  
DISTRICT OF MASSACHUSETTS

**DANA-FARBER CANCER INSTITUTE, INC.**

*Plaintiff*

v.

Civil Action No.:  
**1:10-CV-11613-DPW**

**GATEKEEPER PHARMACEUTICALS, INC.**

*Defendant*

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)*

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.  
Hurst Holme  
12 Trott Rd.  
Hamilton, HM LX  
Bermuda

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiffs attorney, whose name and address are:

Timothy T. Scott, Esq.  
KING & SPALDING LLP  
333 Twin Dolphin Dr., Suite 400  
Redwood Shores, California 94065, USA

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

**SARAH ALLISON THORNTON**

*CLERK OF COURT*

**/s/ – Steve York**

*Signature of Clerk or Deputy Clerk*



Civil Action No.: 1:10-CV-11613-DPW

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for (name of individual and title, if any) \_\_\_\_\_  
was received by me on (date) \_\_\_\_\_.

☐ I personally served the summons on the individual at (place) \_\_\_\_\_  
\_\_\_\_\_ on (date) \_\_\_\_\_; or

☐ I left the summons at the individuals residence or usual place of abode with (name) \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on (date) \_\_\_\_\_, and mailed a copy to the individuals last known address; or

☐ I served the summons on (name of individual) \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of (name of organization) \_\_\_\_\_  
\_\_\_\_\_ on (date) \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other (specify) :

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Server's Signature

\_\_\_\_\_  
Printed name and title

\_\_\_\_\_  
Server's Address

Additional information regarding attempted service, etc:



115000042

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

DANA-FARBER CANCER INSTITUTE,  
INC.,

Plaintiff,

v.

GATEKEEPER PHARMACEUTICALS, INC.,  
Defendant.

Civil Action No. 1:10-CV-11613

GATEKEEPER PHARMACEUTICALS, INC.,  
a Delaware corporation,

Counterclaimant and Cross-  
Claimant,

v.

DANA- FARBER CANCER INSTITUTE,  
INC., a Massachusetts corporation,

Counter-Defendant,

- and -

NOVARTIS PHARMA, A.G., a Swiss  
corporation; NOVARTIS INTERNATIONAL  
PHARMACEUTICAL, LTD., a Bermuda  
corporation; and NOVARTIS INSTITUTES  
FOR BIOMEDICAL RESEARCH, INC., a  
Delaware corporation,

Cross-Defendants.

**AMENDED COUNTERCLAIMS AND CROSSCLAIMS OF GATEKEEPER  
PHARMACEUTICALS, INC.**

**AMENDED COUNTERCLAIMS AND CROSSCLAIMS OF GATEKEEPER  
PHARMACEUTICALS, INC.**

Comes now Gatekeeper Pharmaceuticals, Inc. (“Gatekeeper”), and for its counterclaims against Dana-Farber Cancer Institute, Inc. (“DFCI”), and third-party claims against Novartis Pharma, A.G.; Novartis International Pharmaceuticals, Ltd.; and Novartis Institutes for Biomedical Research, Inc., (hereinafter collectively referred to as “Novartis”) alleges as follows:

**INTRODUCTION**

1. Non-small-cell lung cancer is nearly always a fatal disease. In certain patients, the first or second line treatment of non-small-cell lung cancer is an epidermal growth factor receptor (EGFR) kinase inhibitor, either Iressa and Tarceva. Unfortunately, however, in nearly all non-small-cell lung cancers which responded to Iressa and Tarceva, a resistance to these drugs develops, rendering the drugs impotent against the cancer. Approximately 50% of resistance is due to the T790M mutation in EGFR. Efforts to develop drugs to overcome T790M resistance have been challenging and have resulted in potential drugs that are insufficiently potent to inhibit the T790M version of EGFR or that are too toxic to be administered, primarily because such drugs also attacked wild type, or normal, EGFR, resulting in intolerable side effects. No EGFR -targeted drug exists which overcomes T790M resistance in patients. The physicians and researchers who founded Gatekeeper, Inc., (along with Dr. Chant as President) identified a novel solution to this problem and a series of new compounds based on the approach that appears to be effective against the gatekeeper T790M mutation, but which are not toxic against normal, or “wild type” EGFR, thereby conferring a tremendous competitive advantage to these compounds. The path to approval and commercial sales for such an agent is expected to be rapid and relatively economical. These physicians and researchers were at the time and remain employed by the DFCI.

2. DFCI is a non-profit Massachusetts corporation that conducts research into cancer therapies and treats cancer patients. DFCI receives funding from a variety of sources, including millions of dollars from the United States government. It is also, however, sponsored by and receives funding from Novartis International Pharmaceutical, Ltd., the Bermuda based subsidiary of one of the world's largest pharmaceutical companies, Novartis AG, based in Basel, Switzerland. On information and belief, pursuant to this sponsored research agreement, Novartis International Pharmaceutical, Ltd., and/or its affiliates contributes over \$15 million per year to DFCI.

3. On information and belief, in exchange for its annual contributions to DFCI, Novartis has certain rights of first refusal to obtain licenses to developments funded by Novartis, with certain license terms pre-defined. These rights are reflected in a Collaborative Research Agreement entered into between Novartis International Pharmaceutical and DFCI. In addition to this direct funding, Novartis keeps many of the physicians and researchers at DFCI on its private payroll as consultants and advisors, many of whom (on information and belief) receive more in consulting fees from Novartis than they receive in salary from DFCI.

4. On information and belief, as a result of its approximately \$15 million in annual contributions and its employment as consultants of many of the key decision-makers at DFCI, Novartis is able to dominate much of the decision-making at DFCI, particularly when such decision-making affects the interests of Novartis.

5. When the researchers and physicians who worked at DFCI made their discovery of compounds that might be efficacious against the T790M mutation but not toxic to normal EFGR, they filed a patent application and sought and received permission from DFCI to form a company to exploit their discovery and to bring to market the first drug to treat non-

small-cell lung cancer that had mutated to become resistant to Tarceva or Iressa.

6. Gatekeeper, Inc. was formed by these physicians and researchers, among others, and, through negotiations between Dr. Chant and Anthony Del Campo, Vice President of Office of Research and Technology Ventures, entered into various agreements with DFCI to obtain the rights to develop and commercialize the product. On information and belief, when Novartis discovered the existence of the technology and DFCI's agreement to license the technology to Gatekeeper, it exercised its influence over DFCI to cause DFCI to breach its agreement with Gatekeeper and instead to deliver the technology to the drug giant Novartis for it to exploit.

7. On information and belief, as a consequence of the pressure applied by Novartis, DFCI even went so far as to bring a lawsuit against Gatekeeper in an effort to protect the interests of the drug giant which paid money to DFCI and lined the pockets of its most prominent physicians and researchers.

#### **PARTIES**

8. Gatekeeper Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business in Millbrae, California. Gatekeeper was formed specifically to develop and commercialize the discovery of its founders for treating the gatekeeper T790M mutation in non-small-cell lung cancer. Gatekeeper is in the business of developing and/or acquiring rights to next generation small molecule drugs that overcome resistance arising from treatment by targeted oncology agents. Gatekeeper is a small business, as defined by 15 U.S.C. §632 and 13 C.F.R. 121.5.

9. Plaintiff and Counterclaim-Defendant DFCI is a Massachusetts corporation with its principal place of business in Boston, Massachusetts. DFCI is a 501(c)(3) organization that is a major affiliate of Harvard Medical School. DFCI is a prestigious and leading cancer research

center, the affiliation with which provides physicians and researchers substantial stature and benefits, including research and funding opportunities and professional network. DFCI seeks to perform cancer research and to provide care to cancer patients. DFCI is also in the business of conducting research and exploiting the products of that research through a licensing program to generate revenue through the payment of royalties by licensees.

10. On information and belief, Novartis Pharma, A.G. is a Swiss corporation with its principal place of business in Basel, Switzerland. Novartis is in the business of developing or acquiring pharmaceutical products and marketing and selling such products worldwide. Novartis International Pharmaceutical, Ltd. is a wholly owned subsidiary of Novartis AG and is organized under the laws of Bermuda with its principal place of business in Bermuda. Novartis International Pharmaceutical, Ltd. is the Novartis entity that entered into the Collaborative Research Agreement with DFCI and which possesses rights of first refusal to license certain intellectual property from DFCI. Novartis Institutes for Biomedical Research, Inc., is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Novartis Institutes for Biomedical Research, Inc., is an assignee of the Collaborative Research Agreement originally entered into between Novartis International Pharmaceutical and DFCI. On information and belief, Novartis Institutes for Biomedical Research, Inc., is the Novartis entity that is currently pursuing a development program based upon the discovery, compounds and Intellectual Property that is the subject of this crosscomplaint. Novartis Pharma, A.G.; Novartis International Pharmaceutical, Ltd.; Novartis Bioscience, Inc.; and Novartis Institutes for Biomedical Research, Inc., are hereinafter collectively referred to as “Novartis.”

#### **JURISDICTION AND VENUE**

11. Because the counterclaims and third party claims arise out of the same set of

facts as the claims asserted by DFCI in this action, this Court has supplemental jurisdiction on the counterclaims and third party claims asserted herein. Venue is proper in the District of Massachusetts because certain of the conduct that gave rise to the causes of action asserted herein took place in this district.

### **BACKGROUND FACTS**

12. Dr. Nathanael S. Gray is a leading medical chemist. Drs. Wong and Janne are leading clinical oncologists. All three are researchers at and are employed by DFCI. All conduct extensive research into compounds that have potential as therapeutic agents for the treatment of disease and other medical conditions. Much of the work performed by Drs. Janne and Gray and their staff in their laboratories is funded by specific grants and other contributions.

13. Years ago, Drs. Janne and Gray began work on the gatekeeper T790M mutation in non-small-cell lung cancer. That work was performed pursuant to grants provided by the National Institute of Health R01CA11446, R01CA135257, R01CA130876, from the National Cancer Institute Lung SPORE P50CA090578, from the Hazel and Samuel Bellin Research Fund and the Damon Runyon Foundation Cancer Innovation Award. Novartis played no role in funding the research that resulted in the discoveries that are the subject of this litigation. The research funded by the contributors identified above focused on using a different chemical backbone than Iressa and Tarceva to develop compounds that are effective against T790M resistant EGFR kinases while only weakly affecting normal EGFR. This research resulted in a series of compounds and associated intellectual property that shows great promise in the fight against non-small-cell lung cancer.

14. Shortly after discovering the new compound, the Gatekeeper founders, including Dr. Janne and Gray, approached DFCI to seek permission to form a new entity to

develop and commercialize the compounds. DFCI approved this approach and the new entity, Gatekeeper, was formed in March 2009. Gatekeeper subsequently sought and obtained outside investments from third parties. Gatekeeper also employed executive officers, including Dr. Chant, without paying such officers any compensation other than the promise of equity that would have value once the Intellectual Property was developed and commercialized.

15. On or about April 9, 2009, Gatekeeper and DFCI entered into a Confidentiality Agreement, attached hereto as Exhibit A, to provide for the exchange of information related to various technologies developed in the laboratories of DFCI.

16. On or about June 1, 2009, Gatekeeper and DFCI entered into a valid and enforceable contract attached hereto as Exhibit B (hereinafter the “Option to Acquire”). Pursuant to the contract, Gatekeeper had an option to acquire an exclusive license to certain Intellectual Property including patent rights (the “Intellectual Property”) related to Drs. Janne and Gray’s discovery of the compounds potentially useful for overcoming resistance arising from the gatekeeper T790M mutation. The Option to Acquire contained, among other things, confidentiality provisions that required each party to use “all reasonable diligence to prevent disclosure,” and prevented DFCI from offering a license to the Intellectual Property to any third parties.

17. Prior to entering into the Option to Acquire, DFCI performed thorough due diligence on its right to convey an exclusive license to the Intellectual Property. Among the issues examined at the time by DFCI was whether Novartis had any rights to the Intellectual Property. DFCI’s due diligence was so thorough that it revealed that Gatekeeper, or DFCI on its behalf, would have to make a very small contribution to a foundation that had sponsored some of the work if the Intellectual Property were developed into a product that was marketed publicly,

but the due diligence determined that Novartis had no rights.

18. On information and belief, shortly after the Option to Acquire was entered into by Gatekeeper and DFCI, Dr. David Livingston, a paid consultant to Novartis who works at DFCI as Chair of the Executive Committee for Research and as a Professor, and who leads the Novartis-DFCI collaboration, learned of the Option to Acquire. Upon learning of the option to acquire, Dr. Livingston personally inspected the files of the Office of Research and Technology Ventures at DFCI to personally review the files related to the Option to Acquire and to the Intellectual Property.

19. On information and belief, notwithstanding the confidentiality provisions of the Option to Acquire and the Confidentiality Agreement entered into by Gatekeeper and DFCI, Dr. Livingston and/or other DFCI employees on his behalf immediately alerted Novartis to the discovery of Drs. Janne and Gray, to their non-public patent application, and to the Option to Acquire. This disclosure of the non-public patent application was particularly damaging to Gatekeeper. The patent application discloses the full extent of the scope of the Intellectual Property; knowledge of the extent of the scope allows others to design around the Intellectual Property. On information and belief, Novartis knew at the time of its receipt of a copy of the non-public patent application that it was received from a person or entity who had an obligation to maintain its secrecy or limit its use. Novartis' knowledge and subsequent use of the non-public patent application contaminated Novartis' development program. This disclosure breached the agreements between Gatekeeper and DFCI and caused Gatekeeper immediate and irreparable harm, allowing Novartis to immediately commence development work on bringing the compounds or related compounds to market and/or planning how to design around Gatekeeper's intellectual property rights.



20. On information and belief, upon learning of the discovery of Drs. Janne and Gray and its probable efficacy and commercial value, Novartis determined that it wanted rights to the Intellectual Property and commercialize the technology. Accordingly, on information and belief, Novartis communicated its desire to its paid consultants at DFCI, among them Dr. Livingston. At no time has Novartis had either a contractual right to the Intellectual Property or a good faith basis upon which to claim such a right.

21. On information and belief, notwithstanding the extensive due diligence performed by DFCI prior to entering into the Option to Acquire, Dr. Livingston thereupon commenced an "internal investigation" and an outside review as to whether or not the Intellectual Property and the associated compounds could be viewed as subject to Novartis' option to acquire them.

22. In the summer of 2009, DFCI engaged an outside expert, Dr. Jack Taunton of University of California, San Francisco, to examine the facts and provide his views as to whether Novartis had rights to the Intellectual Property. Dr. Taunton concluded that Novartis had no rights.

23. During 2009 and early 2010, Gatekeeper and its attorneys reviewed the patent filings made by DFCI and determined that certain improvements to those filings could be made to strengthen the nature and extent of the legal protection afforded to the Intellectual Property by the patent laws in order to maximize the potential benefit to Gatekeeper and DFCI. Gatekeeper communicated these improvements to DFCI and DFCI indicated its willingness to make changes to its patent filings in order to accommodate Gatekeeper and strengthen the Intellectual Property.

24. In addition to its work improving the Intellectual Property, Gatekeeper also worked from the Fall of 2009 to the Spring of 2010 on developing commercial partnerships to

fund the development, approval and commercialization of compounds that could be approved and marketed for the treatment of non-small-cell lung cancer. One entity approached by Gatekeeper, one of the world's leading pharmaceutical companies, would have provided Gatekeeper \$10-15 million up front and in early milestone payments, and an additional \$85 million upon proof of concept in man (*i.e.*, after successful Phase I clinical trials). In addition, there were to be additional approval and commercialization milestone payments based on the industry standard. Gatekeeper would also receive ongoing royalty payments from drug sales upon FDA approval of between 5-20%. Other development companies and venture capital firms proposed similar transactions. In addition, venture capital firms and other potential financiers offered financing transactions. Each prospective bidder withdrew upon learning of Novartis' allegations that it had rights to the Intellectual Property.

25. Meanwhile, on information and belief, notwithstanding having learned that the outside experts consulted by DFCI had determined that Novartis had no rights to the Intellectual Property, Novartis sent a letter to DFCI in November 2009 claiming that it, rather than Gatekeeper, had rights to the Intellectual Property.

26. On or about November 24, 2009, Novartis sent to Gatekeeper the letter attached as Exhibit C asserting that Novartis and not Gatekeeper owned the rights to the Intellectual Property. Significantly, this letter refers by number to the non-public patent application filed by Gatekeeper's founders and that is the subject of the Option to Acquire.

27. Gatekeeper duly informed its prospective partners and investors of the letter from Novartis alleging that it rather than Gatekeeper had rights to the Intellectual Property. Upon learning that Novartis had alleged that it was entitled to the Intellectual Property, all of its prospective partners and investors declined to proceed with a transaction with Gatekeeper.

28. In December, 2009, Nature published the letter from Drs. Janne and Gray and their various collaborators announcing their discovery of a compound to address the gatekeeper T790M mutation. The Nature letter discloses three example compounds but the full extent of the Intellectual Property is not disclosed. The letter acknowledged and identified the various sources of funding for the research that resulted in the Intellectual Property, and nowhere is Novartis identified as having provided any funding. In the declaration of competing financial interests statement published by Nature, Drs. Gray and Janne expressly acknowledged that the compounds described in the article “have been licensed to Gatekeeper. . . .” On information and belief, DFCI reviewed and approved this statement. In the accompanying article regarding the compounds directed toward the gatekeeper T790M mutation, Dr. Janne made clear that the Intellectual Property was licensed to Gatekeeper.

29. In the wake of Novartis’ letter, DFCI again consulted an outside expert to provide his views as to whether Novartis had any rights to the Intellectual Property. Barret Rollins, DFCI’s Chief Scientific Officer, undertook to oversee this independent inquiry and retained Professor Greg Verdine at Harvard to conduct the analysis. Like Dr. Taunton, Professor Verdine concluded in March 2010 that Novartis had no rights. DFCI attempted to keep Dr. Verdine’s conclusions secret from Gatekeeper.

30. On information and belief, Novartis continued to pressure DFCI and its paid consultants at DFCI to enable Novartis to obtain the rights to the Intellectual Property. On information and belief, Novartis also began work on a parallel track, attempting to limit the scope of the Intellectual Property such that Novartis could use the information gleaned from DFCI’s non-public patent filings and the information disclosed in the Nature article to develop a compound using Gatekeeper’s approach and trade secrets that addressed the gatekeeper T790M

mutation without technically infringing upon the DFCI patent. On information and belief, toward that end, Novartis instructed DFCI to cease its cooperation with Gatekeeper regarding improvements to the Intellectual Property and, on April 15, 2010, DFCI in fact refused to make such improvements, having previously agreed to do so.

31. On or about April 23, 2010, Gatekeeper exercised its option to acquire the exclusive license that is the subject of the parties' Option to Acquire. Gatekeeper simultaneously presented DFCI with a with a completed draft license agreement based upon the terms reflected in the Option to Acquire and based upon DFCI's standard template license agreement, previously conveyed to Gatekeeper.

32. In June, 2010, not satisfied that three different investigations had determined that Novartis had no rights to the compound. DFCI initiated yet another "investigation" to determine Novartis' ownership rights, if any. The fourth investigation found that the research was not funded by Novartis, but for the first time concluded that Novartis had rights to the Intellectual Property only because Novartis had once provided funding to one of the labs for a *different* research project. If this standard of ownership rights were applied universally, Novartis would have rights to virtually every research result generated by DFCI, notwithstanding the fact that the United States government, via the National Institute of Health, provides millions of dollars in research funds to DFCI and specifically funded the research that resulted in the Intellectual Property. Through its overbroad and overreaching interpretation of its rights of first refusal, Novartis has itself violated, and has caused DFCI to violate, the Bayh-Dole Act, 35 U.S.C. §200-212 and its implementing regulations and guidelines as promulgated by the Secretary of Commerce and the National Institute of Health.

33. The Bayh-Dole Act implements a policy to encourage the maximum

participation of small business firms in the exploitation of inventions funded by the NIH and to promote the commercialization and public availability of inventions made in the United States by United States industry and labor. 35 U.S.C. § 200. It requires recipients of funding, such as DFCI, to obtain Federal approval of any license of any intellectual property developed with NIH funding and requires that preference in licensing be given to small business firms. 35 U.S.C. §202(c)(7). It also requires that any assignee of an invention funded in part with NIH funds agrees to manufacture its products in the United States. 35 U.S.C. §§ 202(c)(8) and 204. While DFCI's original agreement with Gatekeeper reflected in the Option to Acquire reflected these goals, Novartis' claim of rights to the Intellectual Property and DFCI's subsequent acquiescence to such claims violates these provisions, in that it manifests a preference for large rather than small firms, and for foreign rather than domestic firms. Moreover, on information and belief, the NIH has never approved the licensing of the Intellectual Property to Novartis.

34. In implementing the Bayh-Dole Act, the NIH has promulgated guidance to institutions that enter into sponsored research agreements with commercial entities, such as DFCI's agreement with Novartis. *See Federal Register*, Vol. 59, No. 215, November 8, 1994, pp. 55674-79. That guidance provides, among other things, that recipients of NIH funding "should not enter into sponsored research agreements that permit a sponsor to tie up the development of a technology by acquiring exclusive licensing rights to the product of given research results before deciding whether or not it will actively develop and commercialize the product." Novartis' claim of rights to the Intellectual Property and DFCI's acquiescence to such claims violates this principle and allowed Novartis to tie up the Intellectual Property before it had determined to exploit it. The guidance provides that sponsored research agreements should be subjected to heightened scrutiny and likely violate the Bayh-Dole Act if two of the following three factors are

satisfied: the amount of financial support from the sponsor is more than \$5 million, the sponsor's licensing rights cover all technologies developed by a major group or component of the organization, such as an entire laboratory or department, or the duration of the agreement is more than 5 years. The sponsored research agreement between DFCI and Novartis violate this provision because the funding is greater than \$5 million and, as recently interpreted by Novartis and as apparently acquiesced in by DFCI, Novartis has alleged rights to every invention developed by any laboratory that has received any funding by Novartis. In addition, the guidance suggested that no sponsored research agreement should be "so broad that the subsequent exclusive licensing of technology under the agreement provides a single sponsor with access to a wide array of Recipient research findings and technologies that effectively exclude other organizations from reasonable access to a Recipients technology." This is exactly the result of the sponsored research agreement between Novartis and DFCI, under the position advanced by Novartis and acquiesced in by DFCI.

35. Acquiescing to pressure from its corporate sponsor Novartis, and in breach of its obligations under the Option to Acquire, DFCI informed Gatekeeper that it did not intend to perform its obligations under the Option to Acquire. A copy of this communication is attached as Exhibit D.

36. On information and belief, in conscious and reckless disregard of the rights of Gatekeeper, Novartis has begun development of the Intellectual Property into an approvable and commercially viable product for the treatment of non-small-cell lung cancer. On information and belief, prior to the receipt of the non-public patent application alleged above, Novartis had no EGFR program designed to address the Tarceva and Iressa resistance market; only after receipt of the non-public patent application did Novartis commence such a program. Such

development work relies, in large part, upon the inappropriate disclosure by DFCI of trade secrets and other information to which only Gatekeeper had exclusive rights, all in violation of the Confidentiality Agreement and the Option to Acquire.

### **COUNT I**

#### **(For Specific Performance Against DFCI)**

37. Gatekeeper repeats and realleges the allegations set forth in paragraphs 1 through 36 above as though fully set forth herein.

38. Gatekeeper has performed all conditions required to be performed by it under the terms of the Option to Acquire.

39. Notwithstanding Gatekeeper's performance of its obligations under the Agreement, DFCI refuses to be bound, refuses to negotiate a license agreement, and has stated it will not honor its obligations under the Option to Acquire. See Exhibit D.

40. DFCI conduct alleged above constitutes a breach of the Option to Acquire.

41. The Intellectual Property rights that are the subject of the Option to Acquire are unique and irreplaceable.

42. Gatekeeper has been irreparably harmed by DFCI's refusal to license the Intellectual Property as required by the Option to Acquire and by its refusal to cooperate in incorporating improvements to the patent application as suggested by Gatekeeper's attorneys.

43. Gatekeeper has no adequate remedy at law for DFCI's refusal to license the Intellectual Property as required by the Option to Acquire.

### **COUNT II**

#### **(In the Alternative, For Breach of Contract Against DFCI)**

44. Gatekeeper repeats and realleges the allegations set forth in paragraphs 1

through 36 above as though fully set forth herein.

45. DFCI's disclosure to Novartis of the unpublished patent application with respect to the Intellectual Property constituted a breach of the Confidentiality Agreement and a breach of the Option to Acquire.

46. Notwithstanding Gatekeeper's performance of its obligations under the Agreement, DFCI refuses to be bound, refuses to negotiate a license agreement, and has stated it will not honor its obligations under the Option to Acquire. See Exhibit D.

47. DFCI conduct alleged above constitutes a breach of the Option to Acquire.

48. Gatekeeper has performed all conditions required to be performed by it under the terms of the Option to Acquire.

49. Gatekeeper has been damaged by DFCI's breach of contract. Such damages include but are not limited to the amounts prospective partners agreed to pay to Gatekeeper to partner with or sub-license the Intellectual Property, lost profits on the commercialization and sale of the Intellectual Property, and lost profits arising from the delay in commercialization of the Intellectual Property caused by DFCI's conduct as hereinabove alleged.

### **COUNT III**

#### **(For Intentional Interference with Contractual Relations Against Novartis)**

50. Gatekeeper repeats and realleges the allegations set forth in paragraphs 1 through 36 and 44 through 49 above as though fully set forth herein.

51. Novartis learned of the Option to Acquire shortly after its execution in April, 2009. Novartis then used the leverage on DFCI that arose by virtue of its \$15 million annual contribution to DFCI and its retention of DFCI scientists as "consultants" to insist to DFCI that it rather than Gatekeeper be given exclusive rights to the Intellectual Property.



52. At the time that Novartis insisted that it be given rights to the Intellectual Property, it knew or should have known that it had no legitimate contractual claim to such rights. Novartis conduct in this regard was specifically designed to induce DFCI to breach its contract with Gatekeeper. The insistence from Novartis, DFCI's primary corporate backer, led directly to DFCI's issuance of the letter attached hereto as Exhibit D.

53. In addition, Novartis conduct in this regard was wrongful. As alleged above in more detail, it violated, and caused DFCI to violate, the Bayh-Dole Act and its implementing regulations and the guidance provided by NIH regarding inventions that result from its funding. Moreover, Novartis' use of the information inappropriately disclosed by DFCI, including but not limited to the unpublished patent application, was wrongful in that Novartis knew at the time that it received such information that it was confidential and that its receipt was from a person or entity who owed a duty to keep such information secret and to limit its use.

54. Gatekeeper has been damaged by Novartis' conduct alleged above, in that Gatekeeper has been deprived of the exclusive license to which it was contractually entitled and, as a consequence, has not been able to commence development of the Intellectual Property into a product for the marketplace.

55. Novartis' conduct in inducing DFCI's breach of contract was willful, malicious and oppressive, undertaken by Novartis with a conscious and deliberate disregard of the rights of Gatekeeper under the Option to Acquire.

#### **COUNT IV**

##### **(For Declaratory Judgment Against DFCI and Novartis)**

56. Gatekeeper repeats and realleges the allegations set forth in paragraphs 1-36 above as though fully set forth herein.

57. Gatekeeper states that an actual controversy exists between DFCI, Novartis, and Gatekeeper regarding the rights and obligations of DFCI under the Option to Acquire and in connection with the rights to the Intellectual Property.

WHEREFORE, Gatekeeper prays for judgment against DFCI and Novartis as follows:

1. That this Court declare that Novartis has no rights to the Intellectual Property, and that the Option to Acquire contract between DFCI and Gatekeeper is valid and enforceable;

2. For a judgment compelling DFCI to specifically perform its obligations under the Option to Acquire and/or for an award of damages from DFCI for breach of contract in an amount to be proven at trial;

3. For damages against Novartis for inducing a breach of contract in an amount to be proven at trial;

4. For imposition of a constructive trust on any and all profits generated by Novartis from the development and commercialization of the Intellectual Property;

5. For exemplary damages against Novartis in an amount sufficient to punish Novartis;

6. For an award of attorney's fees; and

7. For such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Gatekeeper Pharmaceuticals, Inc., hereby demands a trial by jury in this action of all issues so triable.

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Dated: January 20, 2011

Respectfully submitted,

DEFENDANT, COUNTERCLAIMANT  
AND CROSS-CLAIMANT GATEKEEPER  
PHARMACEUTICALS, INC.

By its attorneys,

/s/ Timothy T. Scott

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants, as identified on the Notice of Electronic File ("NEF"), and paper copies will be sent to those indicated as non-registered participants on January 20, 2011 by first class mail.

/s/ Timothy T. Scott

Timothy T. Scott

# **EXHIBIT A**

## CONFIDENTIALITY AGREEMENT

**THIS CONFIDENTIALITY AGREEMENT** (this "Agreement") is made and entered into as of April 2, 2009 (the "Effective Date") between Gatekeeper Pharmaceuticals ("Company") having offices at 1170 Tuolumne Court, Millbrae, CA, 94030 and Dana-Farber Cancer Institute ("DFCI") having its principal place of business at 44 Binney Street, Boston, MA, 02115. For the purposes of this agreement, both of the above mentioned parties (hereafter individually a "Party" and collectively the "Parties") may participate as both the "Receiving" or the "Disclosing" Party mentioned below and are therefore mutually subject to the conditions and terms of each.

1. **Background.** Company and DFCI intend to engage in discussions regarding the potential licensing of various technologies developed in laboratories at DFCI (the "Subject Matter"). In the course of such discussions and negotiations, it is anticipated that Company and DFCI will mutually disclose or deliver to other Party certain trade secrets or confidential or proprietary information related to the Subject Matter for the sole purpose of enabling both Parties to evaluate the scientific and technical merit and commercial potential thereof. Company and DFCI have entered into this Agreement in order to assure the confidentiality of such trade secrets and confidential or proprietary information in accordance with the terms of this Agreement.

2. **Proprietary Information.** As used in this Agreement, the term "Proprietary Information" shall mean all trade secrets or confidential or proprietary information designated as such in writing, whether by letter or by the use of an appropriate proprietary stamp or legend, prior to or at the time any such trade secret or confidential or proprietary information is disclosed by the Disclosing Party to the Receiving Party. Notwithstanding the foregoing, information which is orally or visually disclosed to the Receiving Party by the Disclosing Party, or is disclosed in writing without an appropriate letter, proprietary stamp or legend, shall constitute Proprietary Information if it would be apparent to a reasonable person, familiar with the Disclosing Party's business and the industry in which it operates, that such information is of a confidential or proprietary nature the maintenance of which is important to either Party. In addition, the term "Proprietary Information" shall be deemed to include any notes, analyses, compilations, studies, interpretations, memoranda or other documents prepared by the Receiving Party which contain, reflect or are based upon, in whole or in part, any Proprietary Information furnished by the Disclosing Party.

3. **Use and Disclosure of Proprietary Information.** The Receiving Party shall hold in confidence, and shall not disclose to any person, any Proprietary Information of the Disclosing Party other than to those of its officers, employees, or consultants who require access to the Proprietary Information for purposes permitted hereunder, and that all such disclosures shall be subject to contractual obligations of confidentiality at least as restrictive as those in this Agreement. The Receiving Party shall use such Proprietary Information only for the purpose for which it was disclosed and shall not use or exploit such Proprietary Information for its own benefit or the benefit of another without the prior written consent of the Disclosing Party.

4. **Limitation on Obligations.** The obligations of the Receiving Party specified in Section 3 above shall not apply, and the Receiving Party shall have no further obligations, with respect to any Proprietary Information to the extent the Receiving Party can demonstrate, by clear and convincing evidence, that such Proprietary Information:

(a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of the Receiving Party;

(b) is in the Receiving Party's possession at the time of disclosure otherwise than as a result of Recipient Party's breach of any legal obligation;

(c) was lawfully received by the Receiving Party from a third party having a right of further disclosure and who did not receive such information from the Disclosing Party; or

(d) was independently developed by the Receiving Party without reference to or reliance upon the Proprietary Information.

Notwithstanding anything to the contrary in this Agreement, the Receiving Party shall have the right to disclose such Proprietary Information of the Disclosing Party that is required to be disclosed by the Receiving Party to comply with applicable laws or governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the extent of such disclosure.

5. Ownership of Proprietary Information. The Receiving Party agrees that the Disclosing Party is and shall remain the exclusive owner of the Proprietary Information and all patent, copyright, trade secret, trademark and other intellectual property rights therein. No license or conveyance of any such rights to the Receiving Party is granted or implied under this Agreement. Each of the Parties represent and warrant that the Proprietary Information which it discloses to the other Party pursuant to this Agreement has not been stolen, appropriated or converted without authorization.

6. Return of Proprietary Information. The Receiving Party shall, upon the termination of this Agreement or the request of the Disclosing Party, return to the Disclosing Party all drawings, documents and other tangible manifestations of the Disclosing Party's Proprietary Information received (and all copies and reproductions thereof) and shall destroy any notes, analyses, compilation, studies, interpretations, memoranda or other documents prepared by the Receiving Party which contain, reflect or are based upon any such Proprietary Information. .

7. Miscellaneous.

(a) This Agreement supersedes all prior agreements, written or oral, between the Parties relating to maintaining the confidentiality of Proprietary Information related to the Subject Matter.. This Agreement may not be modified, amended or discharged, in whole or in part, except by an agreement in writing signed by both Parties.

(b) This Agreement will be binding upon and inure to the benefit of the Parties and their respective heirs, successors and assigns.

(c) This Agreement shall be construed and interpreted in accordance with the internal laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of law thereof.

(d) The provisions of this Agreement are necessary for the protection of the business and goodwill of both Parties and are considered to be reasonable for such purpose.

(e) For the convenience of the Parties, this letter agreement may be executed by facsimile and in counterparts, each of which shall be deemed to be an original, and both of which taken together, shall constitute one agreement binding on both Parties.

(f) This Agreement shall govern the exchange of the Confidential Information by the Parties during a one (1) year term commencing on the date of this Agreement. The term may be extended by written agreement of the Parties. The nonuse and nondisclosure provisions shall apply during the term of this Agreement and, notwithstanding anything in this Agreement to the contrary, shall continue in effect for a period of five (5) years following expiration or termination of this Agreement. Either party may terminate this Agreement without cause upon thirty (30) days prior written notice to the other party. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto.

**IN WITNESS WHEREOF**, the Parties hereby execute this Agreement by their respective duly authorized representatives.

GATEKEEPER PHARMACEUTICALS INC.

Signed: 

Date: April 9, 2009                     

Name: John Chant, President

DANA-FARBER CANCER INSTITUTE

Signed: 

Date: 4/14/09

Name: Anthony A. del Campo, MBA, CLP

Title: Vice-President, Office of Research and  
Technology Ventures

# **EXHIBIT B**



DFCI Agreement No. 3725

#### OPTION AGREEMENT

This Option Agreement, by and among the Dana-Farber Cancer Institute, Inc., having an office at 44 Binney St., Boston, MA 02115 ("DFCI"), and Gatekeeper Pharmaceuticals, Inc. having an address at 1170 Tuolumne Court, Millbrae, CA 94030 ("Gatekeeper") is made effective as of June 1<sup>st</sup>, 2009 ("Option Effective Date").

Whereas Gatekeeper desires to obtain a license to certain intellectual property solely owned by DFCI to permit Gatekeeper to commercially develop such intellectual property; and

Whereas DFCI wish to license Patent Rights (as later defined) to Gatekeeper, provided that Gatekeeper closes a Financing (as later defined).

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein and intending to be legally bound hereby, the parties hereto agree as follows:

#### ARTICLE I – Definitions

- 1.1 "Patent Rights" shall mean the patent rights as listed in the attached Exhibit B, plus any conversion, continuation, division or substitution thereon, any reissues, reexaminations or extensions thereof, any continuation-in-part application or patent that is entitled to the priority date of, and is directed specifically to subject matter specifically described in, at least one of the patents or patent applications described above, and any foreign counterparts of any of the foregoing.
- 1.2 "Field of Use" shall mean all therapeutic, diagnostic and prognostic applications relevant to human and/or animal markets. The research reagent market is excluded; provided, however, that use of research reagents in support of Gatekeeper's exercise of the license rights shall be permitted.

#### ARTICLE II – Option Grant

- 2.1 DFCI hereby grants to Gatekeeper an exclusive option ("Option") to enter into an exclusive license to Patent Rights (the "License Agreement"), under terms described in the Term Sheet attached as Exhibit A.
- 2.2 During the Option Period, as defined below, DFCI hereby grants Gatekeeper a non-exclusive, non-sublicenseable license, solely for internal research and development use. Such non-exclusive license shall permit Gatekeeper the right to use Patent Rights for (i) the evaluation, including without limitation contract lead optimization work (subject to the prior approval of DFCI, which shall not be withheld unreasonably), and (ii) the purpose of seeking financing from interested investors. The aforementioned non-exclusive license shall terminate upon the earlier of the expiration of the Option Period and any extension thereto or exercise of the Option by Gatekeeper.

**DFCI Agreement No. 3725**

- 2.3 The Company shall not use the names of the DFCI or their employees in any form (written or orally) of fund raising or promotion or in connection with the sale of products, processes, devices, or designs without the prior written approval of DFCI. Notwithstanding the foregoing, Gatekeeper may identify DFCI as (i) the owners of the Patent Rights and (ii) the anticipated licensors of the Patent Rights and (iii) the affiliation of the founding scientists of Gatekeeper.
- 2.4 During the Option Period, DFCI shall not offer a license to the Patent Rights to any third party in the Field of Use.

**ARTICLE III –Term and Consideration**

- 3.1 As compensation for the grant of the Option, Gatekeeper shall reimburse DFCI for all patent expenses associated Patent Rights incurred by DFCI prior to the Option Effective Date (“Patent Expenses”) as follows :
- (a) Twenty five percent (25%) of Patent Expenses upon execution of this Option Agreement. Gatekeeper shall make such payment to DFCI within ten (10) days of receiving an invoice from DFCI.
  - (b) The remaining balance of Patent Expenses after the payment set forth above in 3.1(a) paid to DFCI upon exercise of the Option.
  - (c) Gatekeeper will reimburse DFCI for all ongoing patent expenses associated with Patent Rights incurred by DFCI during the Option Period, (as herein defined) and any extension thereto.
  - (d) In the event, that Gatekeeper does not exercise the Option or otherwise does not enter into a license for the Patent Rights, except due to a breach by DFCI of this Option Agreement, the aforementioned balance of Patent Expenses shall immediately become due and payable to DFCI by Gatekeeper.
- 3.2 Gatekeeper may exercise the Option by providing written notice to DFCI at the addresses listed in Section 6.3 within twelve (12) months after the Option Effective Date subject to any extension as provided below in Article 3.3 hereunder (the “Option Period”), provided that Gatekeeper has received a at least two hundred and fifty thousand dollars (\$250,000) of financing. (a “Financing”). Gatekeeper shall provide DFCI sufficient written evidence of such Financing.
- 3.3 If Gatekeeper exercises the Option during the Option Period, DFCI and Gatekeeper shall thereafter negotiate diligently and in good faith the definitive License Agreement which shall substantially contain the terms and conditions outlined in Exhibit A and such other commercially reasonable terms and conditions that are typical of transactions between academic institutions and industry. For the sake of clarity, Gatekeeper and the DFCI agree not to materially modify or add to the financial terms as outlined in Exhibit A unless as mutually agreed upon by DFCI and Gatekeeper; provided however that no party

**DFCI Agreement No. 3725**

shall be obligated to execute and deliver such definitive License Agreement unless and until Gatekeeper has raised the Financing.

- 3.4 Gatekeeper may extend the initial Option Period, by an additional six (6) months by providing written notice to DFCI prior to the expiration of the Option Period and making a payment of fifteen thousand dollars (\$15,000) to DFCI of which amount shall be nonrefundable. Such payment shall be paid to DFCI by Gatekeeper no later than five (5) days after providing DFCI with written notice to extend the initial Option Period.
- 3.5 Notwithstanding the foregoing, if the parties do not, despite good faith efforts, execute the License Agreement within one hundred eighty (180) days of Gatekeeper's notice to exercise the Option, then the Option shall immediately terminate and the parties shall have no further obligation to the other, provided that Gatekeeper shall remain liable to DFCI for any patent expenses due with respect to Patent Rights (as defined below) and any payment due with respect to the extension of the Option Period, if so extended by Gatekeeper.

**ARTICLE IV – Confidentiality**

- 4.1 The parties acknowledge that they have executed and delivered a mutually acceptable form of reciprocal non-disclosure agreement dated April, 9, 2009 that will remain binding upon them in accordance with its terms. DFCI acknowledge that Gatekeeper may disclose the terms of the Option Agreement to bona fide potential investors, employees, consultants and collaborators as reasonably required and under appropriate confidentiality provisions as defined below.
- 4.2 The parties further agree that any information disclosed pursuant to this Option Agreement shall be maintained in strict confidence and each will use all reasonable diligence to prevent disclosure except as provided for in Article 4.1. The obligations under this confidentiality clause shall remain in effect for the Option Term and a period of five (5) years thereafter. Gatekeeper and the DFCI shall not have any obligation of confidentiality with respect to information that:
- (a) is in the public domain by use and/or publication at the time of its receipt from the disclosing party; or
  - (b) is developed independently of information received from the disclosing party; or
  - (c) was already in the recipients possession prior to receipt from disclosing party; or
  - (d) is properly obtained by recipient from a third party with a valid legal right to disclose such information and such third party is not under a confidentiality obligation to the disclosing party with respect to said information.

DFCI Agreement No. 3725

ARTICLE V – Patent Expenses

- 5.1 DFCI shall use good faith efforts to keep Gatekeeper reasonably apprised of the Patent Expenses and ongoing patent prosecution upon request but no more often than on a monthly basis during the term of the Option Period and any extension thereto as applicable, provided however DFCI will contact Gatekeeper to discuss important prosecution decisions as they arise.

ARTICLE VI – Miscellaneous



- 6.1 DFCI MAKES NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR VALIDITY OF PATENT RIGHTS, CLAIMS, ISSUED OR PENDING WITH RESPECT TO THE PATENT RIGHTS.
- 6.2 This Option Agreement is not transferable and not assignable and any attempt to do so shall be null and void.
- 6.3 Any notice required to be given pursuant to the provisions of this Option Agreement shall be in writing and shall be deemed to have been given at the earlier of the time when actually received as a consequence of any effective method of delivery, including but not limited to hand delivery, transmission by telecopier, or delivery by a professional courier service or the time when sent by certified or registered mail addressed to the party for whom intended the address below or at such changed address as the party shall have specified by written notice, provided that any notice of change of address shall be effective only upon actual receipt.
- To DFCI:  
Vice President, Office of Research and Technology Ventures  
Dana-Farber Cancer Institute, Inc.  
44 Binney Street, BP 309  
Boston, MA 02115  
Email: anthony\_delcampo@dfci.harvard.edu
- To Gatekeeper:  
John S. Chant  
President, Gatekeeper Pharmaceuticals, Inc.  
1170 Tuolumne Court,  
Millbrae, CA 94030
- 6.4 This Option Agreement shall be construed and the rights of the parties determined by the laws of the Commonwealth of Massachusetts without regard from choice of law provisions.
- 6.5 The parties hereto are independent contractors and not joint venturers or partners.

**DFCI Agreement No. 3725**

- 6.6 The parties agree that this Option Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the parties.
- 6.7 This Option Agreement, and the Exhibits attached hereto, contain the entire agreement of the parties hereto with respect to the matter covered hereby and all prior negotiations and agreements with respect hereto are of no force and effect. No subsequent modification hereof shall be made except in writing executed by DFCI and Gatekeeper.

IN WITNESS WHEREOF, the parties have executed this Option Agreement on the dates indicated below.

DANA FARBER CANCER INSTITUTE, INC. GATEKEEPER PHARMACEUTICALS, INC.

  
BY: Anthony A. del Campo, MBA, CLP  
BY: John S. Chant, PhD

ITS: Vice President, Research  
and Technology Venture

ITS: President

DATE: 5/29/2009

DATE: 5/29/09

DFCI Agreement No. 3725

Exhibit A

TERM SHEET

Type of License	DFCI will grant to Gatekeeper and its Affiliates (as later defined) an exclusive, worldwide license under the Patent Rights, as listed on Exhibit B, to make, have made, use, sell, have sold, offer for sale, import, any product or provide any service, and practice any methods in connection therewith, in each case, in the Field of Use (as defined below). For the purposes of this Term Sheet, Affiliates means (i) any corporation or business entity of which fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly by Gatekeeper.
Licensed Product	Any product or commercial service whose manufacture, use or sale would, but for the licenses granted, infringe a Valid Claim of a licensed Patent Right.
Field of Use	All diagnostic, prognostic and therapeutic uses in humans or animals. The research reagent market is excluded; provided, however, that use of research reagents in support of Gatekeeper's exercise of the license rights shall be permitted.
Valid Claim	Valid Claim shall mean either (a) a claim of an issued and unexpired patent or a supplementary protection certificate, which has not been held permanently revoked, unenforceable or invalid by a decision of a court, patent office or other forum of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue), or (b) a claim of a pending patent application that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, <i>provided, however</i> , that Valid Claim shall exclude any such claim in such a pending application that has not been granted within twelve (12) years following the earliest priority filing date for such claim.
Right to Sublicense	<p>Gatekeeper will have the right to grant sublicenses consistent with the terms and conditions of the License Agreement, including the inclusion of provisions that obligate sublicensees to be diligent in bringing the subject matter of the sublicense into commercial use.</p> <p>Gatekeeper shall promptly notify DFCI in writing of the identity of any prospective sublicensee at the time that Gatekeeper enters into a binding term sheet or final sublicense with such prospective Sublicensee. Notwithstanding the foregoing, such notification shall be no less than ten (10) business days after the execution of a binding term sheet or final sublicense with such sublicensee. Gatekeeper shall forward to DFCI a copy of any and all fully executed sublicenses.</p>

**DFCI Agreement No. 3725**

Upon termination of the License Agreement for any reason, and at the written request of any sublicensee, DFCI shall assume Gatekeeper's duties and obligations solely with respect to the Patent Rights under each sublicense granted by Gatekeeper to such sublicensee, provided that such sublicensee is not in default under its sublicense, and provided further that such sublicensee agrees to be bound by applicable provisions of the License Agreement.

It is expressly understood that Gatekeeper shall not grant a sublicense to any company engaged in the sale of tobacco or tobacco-related products without the written consent of DFCI.

**Patent Expenses**

Gatekeeper shall pay DFCI for (i) any patent expenses associated with Patent Rights incurred by DFCI prior to the effective date (hereafter the "Effective Date") of the License Agreement and not already paid by Gatekeeper to DFCI and (ii) all ongoing patent expenses associated with the filing, prosecuting, maintaining and enforcing Patent Rights.

**Equity**

As partial compensation for the exclusive license to Patent Rights, Gatekeeper will issue such number of shares of Gatekeeper founding common stock to DFCI which represents 18% of Gatekeeper's founding stock. Exhibit C reflects the allocation of founding shares in Gatekeeper following the aforementioned stock issuance to DFCI.

**Running Royalty:**

Gatekeeper, its Affiliates, sublicensees or acquirers shall pay DFCI 2.75% of net sales of Licensed Products.

For each Licensed Product, Gatekeeper's obligation to pay running royalties to DFCI shall terminate on a country-by-country basis upon expiration of the last Valid Claim of a licensed patent right covering such product in the applicable country. Such running royalties shall not be subject to royalty stacking deductions.

**Diligence**

Gatekeeper will diligently pursue the development and commercialization of Licensed Products. Such efforts shall be consistent with sound and reasonable business practices and judgment.

Specific diligence will include but not be limited to the following requirements:

- a) Gatekeeper will deliver a written Development Plan to DFCI within sixty (60) days of the Effective Date. Such Development Plan will detail Gatekeeper's plans to utilize the Patent Rights for the development and commercialization of a Licensed Product for an indication in the therapeutic market, and;
- b) Gatekeeper will deliver a written Development and

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Commercialization Report to the Institutions on or before each anniversary of the Effective Date. Such reports will describe the efforts by Gatekeeper, or any Affiliates or sublicensees, to bring one or more Licensed Products to the marketplace. The report shall contain sufficient detail to permit DFCI to monitor Gatekeeper's diligence compliance.

**Financial and Development  
Diligence**

Gatekeeper shall :

- a) Raise a total of at least three million dollars (\$3.0M) of financing within three (3) years of the Effective Date. Such financing may include funds from equity investment or other funding from corporate, government, private or investor sources (excluding debt and funding for services which Gatekeeper is required to perform for the benefit of a third party and
- b) Gatekeeper, its Affiliates, or its sublicensees shall file an Investigational New Drug application (an "IND") or foreign equivalent for at least one (1) Licensed Product in the therapeutic Field of Use within five (5) years of the Effective Date.
- c) Gatekeeper, its Affiliates, or its sublicensees shall file a New Drug Application (a "NDA") or foreign equivalent in the US, Japan or EU member country for at least one (1) Licensed Product in the therapeutic Field of Use within eight (8) years of the Effective Date.

**Developmental and  
Commercialization Milestone  
Payments**

For the first two (2) Licensed Products, in the therapeutic Field of Use, to reach the following milestone, Gatekeeper, its Affiliates, its sublicensees, its acquirers or bona fide commercial partners shall make the milestone payment to DFCI as set forth below:

- (a) One hundred thousand dollars \$(100,000) upon IND approval (or foreign equivalent) for clinical trial testing, payable within ninety (90) days of such event, and;
- (b) Seven hundred thousand dollars (\$700,000) upon NDA approval (or foreign equivalent) for commercial sale, payable within ninety (90) days of such event.
- (c) One million dollars (\$1.0M) upon the achievement of first ten million dollars (\$10.0M) of aggregate gross revenue received from the sale of a Licensed Product in the US, Japan, or EU member country. Such milestone payment shall be payable within thirty (30) days of achievement of such milestone.

For the sake of clarity, payments due under (c) above, shall mean approved indications in the therapeutic Field of Use, whether a first or second approved indication for a Licensed Product, or a first approval of each of a first or second distinct Licensed Product,



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**Sublicensing**

Gatekeeper shall pay DFCI a royalty based on a percentage share of income received by Gatekeeper from sublicensing of Patent Rights. Such revenue shall be defined to include sublicense issue fees, sublicense milestone payments, sublicense maintenance fees, upfront fees, technology access fees, and any similar payments made by sublicensees to Gatekeeper or Affiliates as consideration for sublicenses granted under Patent Rights, collectively "Sublicense Income". Excluded from Sublicense Income are payments made to Gatekeeper, its Affiliates or from sublicensees that are (a) fees for services, (b) payments related to equity investments in Gatekeeper from third parties, (c) equity received by Gatekeeper from third parties, (d) bona fide research funding from third parties or (e) running royalties on the sale of Licensed Products.

Such amounts shall be paid as follows:

- Fifty percent (50%) of Sublicense Income from all sublicensing agreements entered into by Gatekeeper prior to and including the first (1st) anniversary of the Effective Date;
- Twenty percent (20%) of Sublicense Income from all sublicensing agreements entered into by Gatekeeper subsequent to the first (1<sup>st</sup>) anniversary and prior to and including the third (3<sup>rd</sup>) anniversary of the Effective Date; and
- Fifteen percent (15%) of Sublicense Income of all sublicensing agreements entered into by Gatekeeper subsequent to the third (3<sup>rd</sup>) anniversary and prior to and including the fifth (5th) anniversary of the Effective Date;
- Ten percent (10%) of Sublicense Income of all sublicensing agreements entered into by Gatekeeper subsequent to the fifth (5th) anniversary of the Effective Date;

Payments with respect to Sublicense Income shall be non-creditable against any other payment obligations of Gatekeeper under the License Agreement; provided, however, that if Gatekeeper receives Sublicense Income as a result of a sublicense's achievement of one or more Development Milestones with respect to a Licensed Product for which any Development Milestone is due to DFCI as provided above, amounts paid by Gatekeeper to DFCI on account of such Sublicense Income shall be fully creditable against any amounts payable by Gatekeeper to DFCI for such Development Milestones with respect to the same Licensed Product and indication, as relevant. For the sake of clarity, an upfront or signing fee due Gatekeeper from a sublicense shall not be considered a payment of a Development Milestone. In addition, if Gatekeeper receives Sublicense Income as a result of a sublicensee's achievement of a Commercialization Milestone with respect to a Licensed Product for which a Commercialization Milestone is due to DFCI as provided above, amounts paid by Gatekeeper to DFCI on

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account of such Sublicense Income shall be fully creditable against any amounts payable by Gatekeeper to DFCI for such Commercialization Milestones with respect to the same Licensed Product and indication, as relevant.

**Reporting**

The License Agreement will include appropriate financial and diligence reporting obligations of Gatekeeper.

**Termination**

Institutions may terminate the License Agreement if Gatekeeper fails to meet any of the Diligence provisions or payment obligations, following notice of such breach and an opportunity to cure. The License Agreement will include a reasonable cure mechanism for failure to meet diligence milestones due to reasonable delays.

Gatekeeper may terminate the license with respect to Patent Rights at any time on thirty (30) days prior written notice, provided that Gatekeeper shall be obligated to reimburse DFCI for any Patent Expenses incurred by DFCI up to and including the date of termination.

**Other Terms**

The License Agreement shall include other terms typical of licenses between industry and academic entities, including but not limited to indemnification, insurance, retained rights for non-commercial internal research, reserved rights of Federal government and dispute resolution.

**Patent Prosecution**

DFCI will control patent prosecution, at Gatekeeper's expense, with Gatekeeper having reasonable rights of review and input and step-in rights if DFCI wishes to abandon any claim, application or patent.

**Patent Enforcement**

DFCI is responsible to enforcing its Patent Rights. Gatekeeper may request DFCI to take steps to protect Patent Rights when it has reason to believe that there is an apparent infringer. Gatekeeper shall present evidence of such infringement and DFCI will consider such evidence in good faith. DFCI will notify Gatekeeper as to whether it will pursue legal proceeding to protect against the alleged infringement. If DFCI brings a suit against the alleged infringer, Gatekeeper has the right to join DFCI as a party-plaintiff but DFCI shall be lead counsel. DFCI and Gatekeeper shall equally fund the costs of such litigation. .

If DFCI decides not to pursue litigation against the alleged infringer, Gatekeeper shall have the right to initiate the litigation at its expense. In such case, DFCI has a right to join Gatekeeper as a party-plaintiff and fund up to 50% of the legal proceedings. In such a case, Gatekeeper will be lead counsel.

In any legal proceeding brought by DFCI and funded solely by DFCI, any damages or other amounts recovered as a result of the proceeding will be retained by DFCI.

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In any legal proceeding brought by Gatekeeper and funded solely by Gatekeeper, any damages or other amounts recovered as a result of the proceeding will be retained by Gatekeeper but will be treated as Net Sales of Licensed Products.

In any legal proceeding funded jointly by DFCI and Gatekeeper, any damages or other amounts will first be used to reimburse Gatekeeper and DFCI for litigation costs not paid from royalties. The balance, if any, will be divided equally between the Parties.

**Technology Transfer**

DFCI shall engage in a know-how transfer of all relevant data and other tangible embodiments of Patent Rights.

**Assignment**

The rights and licenses of Gatekeeper under the License Agreement shall not be assignable. Notwithstanding the foregoing, Gatekeeper may assign such rights and licenses to a successor of Gatekeeper in connection with a merger, consolidation, or sale of all or substantially all of its assets relating to the agreement upon written approval by DFCI, where such approval shall not be withheld, provided such successor is not i) engaged in the sale of tobacco or tobacco products, or ii) engaged in litigation with DFCI at the time of assignment. For the sake of clarity, the financial terms of the proposed assignment shall not be grounds for withholding approval by DFCI.

**Governing Law**

Commonwealth of Massachusetts, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

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**EXHIBIT B**

**PATENT RIGHTS**

US Patent Application entitled "EGFR Inhibitors and Methods of Treating Disorders", Serial No. TBD, filed May 5, 2009, DFCI Reference No 1338.01

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**EXHIBIT C****Founding Shares of Gatekeeper Pharmaceuticals**

<b>Founders</b>	<b>Initial Shares Approved by board of Gatekeeper on 3/31/2009</b>	<b>Additional Shares to be approved</b>	<b>Total Founding Shares</b>	<b>Percentage Founders following Gatekeeper board approval</b>
Jeffery Engelman	1,000,000	0	1,000,000	14.6%
Nathanael Schiander Gray	1,000,000	0	1,000,000	14.6%
Pasi A. Janne	1,000,000	0	1,000,000	14.6%
Kwok-Kin Wong	1,000,000	0	1,000,000	14.6%
DFCI	0	1,229,000	1,229,000	18%
John S. Chant	500,000	100,000	600,000	9%
Reserved for future allocation	0	1,000,000	1,000,000	14.6%
<b>Total</b>	<b>4,500,000</b>	<b>2,329,000</b>	<b>6,829,000</b>	<b>100%</b>

# **EXHIBIT C**



Scott A. Brown  
Vice President, General  
Counsel and Global Head  
of NIBR Patents

Novartis Institutes for BioMedical Research, Inc.  
250 Massachusetts Avenue  
Cambridge MA 02139

Tel 617 871 5129  
Fax 617 871 3349  
E-Mail: scottbrown@novartis.com

November 24, 2009

VIA FEDEX

Mr. John Chant, President  
Gatekeeper Pharmaceuticals  
1170 Tuolumne Ct.  
Millbrae, CA 94030

Re: Rights in Dana-Farber EGFR Inhibitors

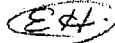
Dear Mr. Chant:

Gatekeeper Pharmaceuticals has had multiple contacts with the Novartis Institutes for BioMedical Research ("NIBR"), an affiliate of Novartis International Pharmaceutical Ltd., (collectively "Novartis") relating to certain inventions made by Dr. Nathaniel Gray, Dr. Michael Eck and others at the Dana-Farber Cancer Institute. Such inventions are believed to be the subject matter of U.S. Patent Application No. 61/215,419 filed by Dana-Farber. Such inventions are subject to an exclusive option to Novartis pursuant an agreement between Novartis and Dana-Farber. Novartis does not know the formal relationship between Gatekeeper and Dana-Farber with respect to these inventions. However, Novartis contends that a grant of any rights to Gatekeeper in such inventions by Dana-Farber is a violation of Novartis' rights under such agreement. As a result, Gatekeeper legitimately holds no rights in such inventions and Gatekeeper's continued assertion of rights in such inventions is legally unfounded.

I can be reached as indicated above if you or your Counsel wish to discuss this matter.

Very truly yours,

A handwritten signature in black ink that reads 'Scott A. Brown'.

Scott A. Brown   
VP, General Counsel and Global Head of NIBR Patents

cc: William Sellers, M.D.

# **EXHIBIT D**



**From:** Brashares, William [mailto:WCBrashares@mintz.com]  
**Sent:** Monday, August 30, 2010 1:45 PM  
**To:** Norviel, Vern  
**Cc:** 'Boskey, Richard S.'  
**Subject:** DFCI-Gatekeeper

Dear Vern:

DFCI has asked us to report to you that we have completed our review of the background of the WZ4002 intellectual property and have concluded that DFCI is unable to convey the license to that property as proposed by Gatekeeper. DFCI remains open to further discussions with Gatekeeper as to possible alternatives.

Ivor Elrifi  
William C. Brashares

William C. Brashares | Member  
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
701 Pennsylvania Ave., NW, Suite 900 | Washington, DC 20004  
Direct: (202) 434-7307 | Fax: (202) 434-7400  
E-mail: [WCBrashares@mintz.com](mailto:WCBrashares@mintz.com)  
Web: [www.mintz.com](http://www.mintz.com)

**MINTZ LEVIN**  
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

<http://sn134w.snt134.mail.live.com/mail/PrintMessages.aspx?cpids=ac643947-b477-11df-...> 1/20/2011